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No.

In The

Supreme Court of the United States

FIDEL ROMERO, Next Friend of Susana Romero, a minor; ANDREA ROMERO, Next Friend of Susana Romero, a minor,

Petitioners,

v.

WYETH, previously known as Lederle Laboratories,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Did Congress intend the broad preemption that the Fifth Circuit found in this case, which includes the preemption of private causes of action of people who are not qualified to access the Vaccine Program, leaving them with no legal recourse in any forum?

II. Did Congress intend to give legislative tribunals, which exist under Article I, the authority to determine if Article III courts have jurisdiction over suits involving private rights?

LIST OF PARTIES

The names of all parties to the proceedings in the court whose judgment is sought to be reviewed here appear in the caption of the case. There is no parent or subsidiary company of any party to be listed.

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PETITION FOR A WRIT OF CERTIORARI

Susana Romero, a minor, by her parents, Fidel Romero and Andrea Romero, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

Petitioner's Motion for Rehearing and Rehearing En Banc were denied on January 10, 2006. App. A, 1a-2a. The non-published opinion of the Fifth Circuit Court of Appeals is reported as *Romero v. Wyeth*, 145 Fed. Appx. 962, 2005 WL 2012359 (5th Cir. (Tex.) Aug. 23 2005). App. B, 3a-6a. The unreported opinion of the district court was entered on September 10, 2004. App. C, 7a-22a.

JURISDICTION

The Court of Appeals denied petitioner's Petition For Rehearing and Rehearing En Banc on January 10, 2006. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

This case involves the interpretation of 42 U.S.C. § 300aa-11, a subsection of the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et sec.* The entirety of subsection 42 U.S.C. § 300aa-11, is reproduced herein as appendix D. App. D, 23a-31a.

STATEMENT OF THE CASE

Susana Romero was born on October 5, 1990, in Texarkana, Texas. On December 12, 1990, after a well baby check, two month-old Susana received a DPT vaccine manufactured by the Defendant, Lederle Laboratories, (now known as "Wyeth"). Susana immediately manifested symptoms of a brain injury. Thirty minutes after Wyeth's DPT vaccine was injected into Susana, she began to seize. Her seizures have never been controlled. She is severely mentally retarded. She is unable to walk and must be pushed in a wheel chair. She is unable to eat and must be fed by a gastric tube. Significantly, Susana's parents did not "incur" the expense of her treatment. The family lives in poverty, and the Texas Medicaid program has paid for Susana's medical care.

On December 3, 2002, Susana's parents filed suit on her behalf against the pharmaceutical manufacturer Wyeth in Federal District Court in the Eastern District of Texas. The District Court had jurisdiction over the claims of Susana Romero by virtue of its diversity jurisdiction in accordance with 28 U.S.C. § 1332. The defendant has admitted to the diversity jurisdiction of the district court. The defendant Wyeth filed a Fed. R. Civ. P. 12(b)(6) Motion to Dismiss on December 30, 2002. Wyeth's 12(b)(6) motion alleged that a provision of the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et sec*, (hereinafter the "Vaccine Program"), specifically 42 U.S.C. § 300aa-11(a)(2), would act as a bar to Susana Romero's suit. App. D, 23a-24a. Subsection 11(a)(2) instructs district court judges to dismiss civil suits filed against vaccine manufactures if the plaintiff has not

first petitioned the Vaccine Program. Susana had not petitioned the Vaccine Program.

The Romero's countered Wyeth's motion by invoking the savings provision from the Vaccine Program, 42 U.S.C. § 300aa-11(a)(9). Subsection 11(a)(9) states that subsection 11(a), which Wyeth had invoked, "applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program." App. D, 26a. Petitioners contended that Susana was never a "qualified" Vaccine Program petitioner because her parents could not satisfy the $1,000 requirement from 42 U.S.C. § 300aa-11(c)(1)(D). App. D, 30a. Subsection 11(c)(1)(D) mandates that Susana's parents had to expend $1,000 of their own money for Susana's care within the first three years of her injury. Medicaid, not Susana's parents, had paid for her care.

After briefing the law, the parties were ordered by the district court to conduct limited discovery on the issue of whether Susana's parents had expended $1,000 as required by subsection 11(c)(1)(D). Both parties submitted evidence to the district court in the form of exhibits and affidavits. In its Order, the district court recited, favorably, the well settled rule that the court must accept as true the non-moving parties well pleaded factual allegations. App. C, 9a. Therefore, the district court accepted as true the Romero's factual contention that Susana had not satisfied the "$1,000" requirement from subsection 11(c)(1)(D).

However, the district court declined to rule on the question of whether Susana was a "qualified" petitioner.

The court instead, *sua sponte,* converted the defendant's Rule 12(b)(6) motion to a Fed. R. Civ. P. 12 (b)(1) Order. The district court held that the Vaccine Program was analogous to the National Labor Relations Act and, hence, was "broadly preemptive." App. C, 14a-16a. The district court held that it was without subject matter jurisdiction to decide if Susana ever met the requirements set by Congress to be a "qualified" petitioner in the Vaccine Program. Therefore, the district court never ruled, one way or the other, whether the savings provision, subsection 11(a)(9), applied to Susana.

The district court's dismissal was appealed to the United States Court of Appeals for the Fifth Circuit. On August 23, 2005 the circuit court affirmed. *See Romero v. Wyeth*, 145 Fed. Appx. 962, 2005 WL 2012359 (5th Cir. (Tex.), Aug. 23 2005).[1] App. B, 3a-6a. The circuit court held, "we find no reversible error in the district court's order," which was that "the district court determined that it lacked subject matter jurisdiction over Appellants' suit because Appellants failed" to file in the Vaccine Program before filing their civil suit. App. B, 5a.

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[1] Unpulished opinions have precedential effect. *Anastasoff v. United States*, 223 F.3d 898 *vac'd as moot on reh'g en banc* 235 F. 3d 1054 (8th Cir. 2000). *See also Committe Rules of Practice & Procedure of the Judicial Conference of the United States* Memorandum Re: Report of Advisory Committee on Appellate Rules, May 6, 2005 (Revised October 7, 2005). The Fifth Circuit's own rules provide that opinions that are designated as "unpublished" "may be cited" and may "be persuasive." (See Fifth Circuit Rule 47.5.4).

A Petition for Panel Rehearing and a Petition for Rehearing En Banc were filed on October 8, 2005. Both were denied, without opinion, on January 10, 2006. App. A, 1a-2a.

REASONS FOR GRANTING THE WRIT

This petition addresses the Fifth Circuit's overly broad interpretation of the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et sec.* (1986). The Fifth Circuit has implied a Congressional intent to preempt that is so broad that it deprives Article III courts of their duty to consider the facts of cases filed in their courts to determine if they have jurisdiction. This implied preemption was applied in this case in a way that deprived the plaintiff of any forum in which to seek redress for her brain injury. If the Fifth Circuit's decision in this case is left undisturbed, the civil remedies of every other similarly situated person, that is, every other vaccine injured person who is not qualified to access the Vaccine Program, will effectively be eliminated.

By providing a savings provision, 42 U.S.C. § 300aa-11(a)(9), Congress intended to preserve the civil remedies of all vaccine injured persons whom Congress deemed non-"qualified" to access the Vaccine Program. The Fifth Circuit's holding in this case has written the savings provision out of the Vaccine Program.

The Fifth Circuit's holding in this case is at odds with this Court's holding in *United States v. Raddatz*, 447 U.S. 667, 681-82 (1980), which stands for the proposition that if a non-Article III tribunal were to preform an

adjudicative function, like deciding whether the Vaccine Program had jurisdiction over a suit or whether jurisdiction properly resides in an Article III court, an Article III court would be obliged to re-determine such a dispute *de novo*.

The Fifth Circuit's decision in this case has also created an intolerable conflict with the earlier Fifth Circuit decision *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004). In *Moss* the Fifth Circuit held that the plaintiffs, who had never filed in the Vaccine Program, were not "qualified" petitioners as that term was defined by Congress in 42 U.S.C. § 300aa-11(c)(1). *Id.* at 505. The court in *Moss* did what the court in *Romero* held that it did not have jurisdiction to do, it determined the jurisdictional facts and applied the savings provision, subsection 11(a)(9), and remanded back to the trial court which had earlier dismissed the case for lack of jurisdiction.

This conflict will require district courts, and circuit courts, throughout the country to chose which line of authority to follow. They now may follow *Moss* and examine the underlying facts and apply the savings provision, subsection 11(a)(9), **or**, they may follow *Romero* and throw all vaccine injury cases out because they lack the jurisdiction necessary to decide whether to apply subsection 11(a)(9).

The Court should exercise its certiorari jurisdiction to ensure that the rights of all vaccine injured people for whom Congress did not provide access to the Vaccine Program have a remedy for their injuries, which was the intent of Congress.

I.

Did Congress intend the broad preemption that the Fifth Circuit found in this case, which includes the preemption of private causes of action of people not qualified to access the Vaccine Program?

A. The Plain Language of the Statute

Both courts below, held that courts of general jurisdiction lack subject matter jurisdiction to consider personal injury suits, like Susana Romero's, if they involve vaccine injuries because the Vaccine Program constitutes a broad preemption of all vaccine injury claims. App. C, 14a-16a and app. B, 5a. The implied preemption found below is so broad that it even deprives federal judges of the authority to examine the facts of a case in their court to determine if the Vaccine Program ever had jurisdiction over the plaintiff or whether jurisdiction properly resides in district court.

The statutory subsection at issue is 42 U.S.C. § 300aa-11(a). The pertinent parts of subsection 11(a) are as follows:

> (2)(A) No person may bring a civil action for damages . . . against a vaccine administrator or manufacturer . . . unless-
> (2)(A)(i) a petition has been filed . . . for compensation under the Program.
> (9) This subsection applies only to a person who has sustained a vaccine-related injury or death and *who is qualified to file a petition* for

compensation under the Program.

See: App. D, 23a-24a and 26a. (Emphasis added.)

The broad jurisdictional preemption found by the courts below is not found in the language of the statute. Instead, Congress included subsection 11(a)(9), the savings provision, which explicitly provides that the rights of vaccine injured people who do not qualify to access the Vaccine Program are preserved.

An earlier decision from the Fifth Circuit Court of Appeals, *Moss*, 381 F.3d 501 (2004), correctly analyzed the doctrine of implied preemption. The Court in *Moss* held that:

> "the Vaccine Defendants contend that the district court properly dismissed the Mosses' claim because they are implicitly preempted by the Vaccine Act. We reject this argument, too, for we will not lightly infer that Congress has implicitly preempted state claims using an instrument that explicitly preempts other claims, see, e.g., *Frieghtliner Corp. v. Myrick*, 514 U.S. 280, 288, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995), and the Vaccine Defendants offer no persuasive reason to make that inferential leap in this case. *Accord Schafer*, 20 F.3d at 6-7. Congress could not have been much more plain in its desire *not* to preempt tort claims filed by persons who are ineligible to recover in the Vaccine Court."

Id. at 506. Emphasis in original.

The court in *Moss* also held:

> "Just as the Vaccine Act does not protect all defendants, it does not apply to all tort suits having some connection to the administration of a vaccine. Rather, the restriction on filing tort claims applies only to those who have 'sustained a vaccine-related injury or death and who [are] qualified to file a petition for compensation under the Program.' § 300aa-11(a)(9)."

Id. at 505, (brackets in the original).

The Court in *Moss* explained that, "the Vaccine Act treats 'the tort suit procedural bar and Vaccine Court compensation as opposite sides of the same coin.'" *Id.* at 505, citing *Schafer v. American Cyanamid*, 20 F.3d 1, 5 (1st Cir.1994).

Another Vaccine Program subsection that mitigates against the Fifth Circuit's broad preemption holding is 42 U.S.C. § 300aa-22(e) (1986). There Congress set limits on States passing or enforcing laws that effect individuals rights to sue for vaccine injuries. By this subsection, Congress is preserving civil remedies, not preempting them.

B. The Doctrine of Sovereign Immunity

The Vaccine Program is a compensation program. Congress, by establishing the Vaccine Program, granted a limited waiver of sovereign immunity, allowing itself to be sued for money damages. (The Secretary of the Department of Health and Human Services is the named respondent when a Vaccine Program petition is filed.)

Since the Vaccine Program is a federal compensation program, any person who wishes to access the Vaccine Program is confronted with the doctrine of "limited waiver of sovereign immunity." Unless a vaccine injured person fits within the unequivocally expressed and narrowly construed waiver of sovereign immunity granted by Congress, the Vaccine Program never gains jurisdiction over their claimed vaccine injury. A Vaccine Program special master discussed this aspect of the Vaccine Program in *Burch ex rel. Burch v. Sec. of Dep't of Health and Human Servs.*, 2001 WL 180129 (Fed.Cl.Spec.Mstr., 2001), where he observed that "recent decisions firmly entrench the rule that statutory waivers of sovereign immunity must be unequivocally expressed, and that the statutory language of such waivers must be strictly and narrowly construed in favor of the government." *Id.* at *4.

42 U.S.C. § 300aa-11(b)(1)(A) provides in pertinent part that "any person who has sustained a vaccine-related injury . . . may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program." App. D, 27a. Unless a vaccine injured person satisfies all of the jurisdictional requirements of subsection 11(c)(1), within the three year statute of limitations,

Congress has not waived the Government's sovereign immunity and the Vaccine Program never gains jurisdiction over their vaccine injury. 42 U.S.C. § 300aa-11(c)(1) (1993), *amended by* 42 U.S.C. § 300aa-11(c)(1) (1998) contains the following requirements:

> (c)(1) – An affidavit must be filed attesting that the vaccine injured person:
> (c)(1)(A) – received a vaccine covered by the program.
> (c)(1)(B) – the vaccine must have been received in the United States. (With some exceptions)
> (c)(1)(C) – the person must have suffered an injury.
> (c)(1)(D) – the injury lasted for at least 6 months and at least $1,000 in out of pocket expenses were incurred because of the injury, or the person died.
> (c)(1)(E) – no previous award from a civil action.

App. D, 27a-30a.

The Romero's could not satisfy the $1,000 out-of-pocket provision from subsection 11(c)(1)(D) because Medicaid had paid for Susana's care. To satisfy this requirement Susana's parents needed to incur $1,000 in out-of-pocket expenses as a result of her vaccine injury within the three year statute of limitations after her injury, or between December 12, 1990 and December 12, 1993.[2]

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[2] In 1998, some five years after Susana Romero's

(Continued . . .)

The district court recited, favorably, the well settled rule that the court must accept as true the non-moving parties well pleaded factual allegations. App. C, 9a. Therefore, the district court accepted as true the Romero's factual contention that Susana did not satisfy the $1,000 requirement and, hence, had not satisfied the requirements of subsection 11(c)(1).

The doctrine of "limited waiver of sovereign immunity" has been used during the history of the Vaccine Program to limit access to categories of vaccine injured people who could not satisfy all of the jurisdictional requirements enumerated in 42 U.S.C. § 300aa-11(c)(1). The doctrine of sovereign immunity was applied to vaccine injured children on Medicaid, like Susana Romero, who could not satisfy the $1,000 requirement, in *Rodriguez v. Sec. of Dep't of Health & Human Servs.*, No. 90-2631V, 1995 WL 273952 (Cl. Ct. Spec. Mstr. April 25, 1995). The special master in *Rodriguez* held that "strict construction of waivers of sovereign immunity necessitates holding that Congress may indeed differentiate between classes of petitioners for whom it is creating a benefit at the expense of the public fisc, which is not endless." *Id.* at *2. The Special Master observed that "the majority of injured vaccinees are not on Medicaid or dependents of

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(. . . Continued)
three year statute of limitations had run, Congress amended 42 U.S.C. § 300aa-11(c)(1), by repealing the $1,000 requirement. See *Pub. L. No.* 105-277, §1502 (1998). This change was not made retroactive and had no effect on Susana Romero, or other similarly situated children.

military personnel. For these families, this Act is a long-awaited relief from interminable and frustrating litigation in the traditional tort system." *Id.* The same logic, and result, from the *Rodriguez* case was applied to a child living on an Indian Reservation in *Black v. Sec. of Dep't Health & Human Serv.*, 33 Fed. Cl. 546, 550 (1995).

The doctrine of sovereign immunity was applied by a special master in *Burch v. Sec. of Dep't Health & Human Serv.*, 2001 WL 180129, *11 (Fed.Cl.Spec.Mstr.), when he held that children who suffer vaccine injuries in utero cannot satisfy the jurisdictional requirements of subsection 11(c)(1)(A).

The doctrine of sovereign immunity was applied in *McGowan v. Sec. of Dep't Health & Human Serv.*, No. 90-2446V., 31 Fed.Cl. 734, (Fed.Cl. 1994), to deny entry into the Vaccine Program to a person who received a vaccine in Canada and did not return to this country quickly enough. The court held that "petitioner has failed to 'return' within the meaning of 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III) and fails to meet the jurisdictional requirements of the Vaccine Act." *Id.* at 740.

The Federal Circuit Court of Appeals in *Black v. Sec. of Dep't Health & Human Servs.*, 95 F.3d 781 (Fed. Cir. 1996) held that:

> A person seeking compensation under the Vaccine Act must file a petition for compensation. A person may file such a petition if he or she "meets the requirements of subsection(c)(1)" of section 11 of the Act,

> 42 U.S.C. § 300aa-11(c)(1). One of those requirements is that the person with the vaccine-related injury suffer the effects of the injury for more than six months and "incurred unreimbursable expenses due in whole or in part" to the injury "in an amount greater than $1,000." 42 U.S.C. § 300aa-11(c)(1)(D).

Id. at 785.

The Federal Circuit went on to hold that, "[t]he statute makes clear that the $1,000 in expenses is a threshold criterion for seeking entry into the compensation program." *Id.* at 787. "While Congress might have settled on different eligibility criteria, it was not obligated to extend the coverage of the Act to all persons suffering any vaccine-related injury." *Id.* at 788. "Thus, Congress has in effect determined that if the $1,000 threshold is not reached within the limitations period, a would-be Vaccine Act petitioner cannot file a timely and qualifying petition." *Id.* at 791.

The Fifth Circuit's decision in this case has effectively eliminated the rights of all the vaccine injured children who, as described above, could not satisfy all of the jurisdictional requirements of subsection 11(c)(1). This includes children of military families and children of the poor who were injured between October 1, 1988, (the effective date of the Vaccine Act) and 1998, when the $1,000 requirement was eliminated. If these families did not spend $1,000 of their own money on their injured child's care, within their three year statute of limitations,

then they never had access to the Vaccine Program. Now, as a result of the *Romero* decision, they are also denied access to courts of general jurisdiction.

It is highly unlikely that any trial judge, State or Federal, would allow a case like Susana Romero's to proceed as long as a federal circuit level decision exists which holds that trial courts lack the jurisdiction necessary to adjudicate the case. These children's rights have been effectively extinguished by the *Romero* decision, contrary to the express wishes of Congress, stated in the savings provision, subsection 11(a)(9). This unjust result should be seen as intolerable by this Court.

If vaccine injured persons must go through the Vaccine Program, at the peril of losing their civil remedies, even if the Vaccine Program does not have jurisdiction over their claims, then this Court should grant this writ and make that pronouncement. The citizens of this country, who receive vaccines and have their children vaccinated, have a right to know what they must do to preserve their rights.

C. THE AFFIDAVIT REQUIREMENT

Subsection 11(c)(1) also requires petitioners to file an affidavit swearing that they satisfy all of the provisions of 11(c)(1). Another apparent result of the *Romero* decision is that non-"qualified" vaccine injured persons, or the parents of non-"qualifying" children, are now required to file false affidavits in the Vaccine Program in order to preserve their civil remedies. This is exactly what Susana Romero's parents would have had to do in order to file a

petition on her behalf.

The Circuit Court in *Moss*, 381 F.3d 501 (5th Cir. 2004), held that the Mosses ability to file an affidavit stating that they satisfied the requirements of subsection 11(c)(1) was of "singular importance." *Id.* at 505. Because they were unable to do so they were "ineligible to file a petition" and "the Vaccine Act's restriction on the filing of tort suits does not apply to them, see § 300aa-11(a)(9)." *Id.*

United States Court of Federal Claims also addressed the affidavit requirement in *Black*, 33 Fed. Cl. 546 (1995), when it held, "this Court holds that the requirements of subsection 11(c) are indeed jurisdictional and that a potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." *Id.* at 550.

It should be self evident that Congress would not require the Romeros, and other similarly situated people, to file false affidavits in a federal program, in order to preserve their civil remedies.

II.

Did Congress intend to give legislative tribunals, which exist under Article I, the authority to determine if Article III courts have jurisdiction over suits involving private rights?

The Fifth Circuit's holding below contravenes this Court's doctrine that persons who assert private rights --

claims against other individuals and not the government – are entitled to jury trials in Article III tribunals. In *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989), this Court held that "[t]he Seventh Amendment protects a litigant's right to a jury trial only if a cause of action is legal in nature and it involves a matter of 'private right.'" *Id.* at 42, n. 4. In *Northern Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982), this Court held that "Congress cannot 'withdraw from [Art. III] judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty.'" *Id.* at 70. (Brackets in the original. Citation omitted.) This Court further held that "it is also clear that even with respect to matters that arguably fall within the scope of the 'public rights' doctrine, the presumption is in favor of Art. III courts." *Id.* "Moreover, when Congress assigns these matters to administrative agencies, or to legislative courts, it has generally provided, and we have suggested that it may be required to provide, for Art. III judicial review." *Id.*

Also see, *United States v. Raddatz*, 447 U.S. 667, 681-82 (1980), for the proposition that if a non-Article III tribunal "determined" the jurisdictional facts, an Article III court would be obliged to re-determine such a dispute *de novo*. In other words, even if an Article I, Vaccine Program special master, were to make a finding that might effect a jurisdictional determination in an Article III court, the Article III judge should not be constrained in the least by that finding. He needs to determine those facts himself, *de novo*.

Article III serves to protect "the role of the

independent judiciary within the constitutional scheme of tripartite government," *Commodity Futures Trading Com'n v. Schor*, 478 U.S. 833, 848 (1985) citing *Thomas v. Union Carbide Agr. Products Co.*, 473 U.S. 568, 583 (1985). A litigant has the right to an adjudication "in a constitutionally proper forum." *Id.* at 579. This Court has many times recognized "[t]he concept of the absolute duty of judges to hear and decide cases within their jurisdiction." *See, United States v. Will*, 449 U.S. 200, 215 (1991) and cases cited therein.

The *Romero* decision also stands for the proposition that Vaccine Program special masters are required to issue advisory opinions in cases where they lack jurisdiction. The court below wanted an Article I Vaccine Program special master, who is an adjunct to the United States Court of Federal Claims, to perform jurisdictional fact finding so that he, an Article III judge, would know if he had jurisdiction to hear a case involving a "private right." The trial court held that "Congress requires that persons who allege vaccine-related injuries are to first file a petition in the Vaccine Court for a determination of whether the Act applies to them before they file a civil action in state or federal court." App. C, 17a. Similarly, the Fifth Circuit held that vaccine injured persons are required to "first seek redress in the specialized United States Court of Federal Claims (the 'Vaccine Court') before attempting to obtain relief in a court of general jurisdiction." App. B, 4a.

Susana Romero, and every other vaccine injured person in this Country who is not qualified to access the Vaccine Program, has been adversely effected by the

abdication of judicial responsibility that is mandated by the *Romero* decision. Review is appropriate to clarify the role of Article III judges in civil vaccine cases.

III

The Conflict

The *Romero* decision has also created a direct conflict with the earlier Fifth Circuit Court of Appeals decision, *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004). The Circuit Court in *Moss* looked at the facts of a vaccine case and determined that the plaintiffs could not satisfied the jurisdictional requirements of subsection 11(c)(1)(A). Therefore the court in *Moss* applied the savings provision, subsection 11(a)(9), and remanded back to the district court, which had earlier dismissed for lack of jurisdiction. This occurred even though the plaintiffs in *Moss* never filed a petition with the Vaccine Program. This is exactly what the Fifth Circuit refused to do, claiming lack of subject matter jurisdiction, in the *Romero* case. Now defendant's in civil vaccine cases, (the pharmaceutical industry), will argue that the more recent decision from the Fifth Circuit, *Romero,* is the better law. Therefore, the argument will go, district courts lack jurisdiction over vaccine injury claims regardless of whether the Vaccine Program ever had jurisdiction. This conflict will allow, and require, district court judges, and circuit courts, throughout the Country to choose which line of authority to follow. They now may follow *Moss* and examine the underlying facts and apply the savings provision, subsection 11(a)(9), **or**, they may follow *Romero* and throw all vaccine injury cases out because

they lack the jurisdiction necessary to decide whether to apply subsection 11(a)(9).

This conflict warrants review. The trial and appellant courts in this country need to know which line of authority is correct.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 04-41316

FIDEL ROMERO, Next Friend of Susana Romero, a minor; ANDREA ROMERO, Next Friend of Susana Romero, a minor
Plaintiffs - Appellants

v.

WYETH, previously known as Lederle Laboratories, et al.
Defendant - Appellee

Filed Jan. 10, 2006

ON PETITION FOR REHEARING AND REHEARING EN BANC

Before WIENER, DeMOSS, and PRADO, Circuit Judges
PER CURIAM:

(X) The Petition for Rehearing is DENIED and no member of this panel nor judge in regular active service on the court having requested that the court be polled on Rehearing En Banc, (FED. R. APP. P. and 5" CIR. R. 35) the Petition for Rehearing En Banc is also DENIED.

ENTERED FOR THE COURT

APPENDIX B

UNITED SATES COURT OF APPEALS
FIFTH CIRCUIT.

No. 04-41316

FIDEL ROMERO, Next Friend of Susana Romero, a minor; ANDREA ROMERO, Next Friend of Susana Romero, a minor
Plaintiffs - Appellants

v.

WYETH, previously known as Lederle Laboratories, et al.
Defendant - Appellee

Filed Aug. 23, 2005

Before WIENER, DeMOSS, and PRADO, Circuit Judges.

PER CURIAM: [FN*]

Appellants Fidel Romero and Andrea Romero, as next

friends of their minor daughter, filed suit against Wyeth, seeking damages for permanent injuries suffered by the child after she was administered a vaccine manufactured by Wyeth.[FN2] Wyeth filed a motion to dismiss, arguing that Appellants' claim failed to comply with the mandatory requirements of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or the "Act"). The district court granted Wyeth's motion and Appellants timely filed the instant appeal.

The Vaccine Act was enacted by Congress "to develop new vaccines, improve existing vaccines, and compensate individuals who have been injured by vaccines routinely administered to children." *Lowry ex rel. Lowry v. Sec'y of Health & Human Servs.*, 189 F.3d 1378, 1381 (Fed.Cir.1999) (citing H.R. Rep. 99-908, at *1, reprinted in* 1986 U.S.C.C.A.N. 6344, 6344). This compensatory program ensures swift compensation for victims of vaccine-related injuries while protecting the nation's supply of vaccines from the costs and risks associated with traditional tort actions. *Moss v. Merck & Co.*, 381 F.3d 501, 503 (5th Cir.2004); *see also Lowry*, 189 F.3d at 1381 (citation omitted). While the statutory scheme provides victims' awards "quickly" and with "generosity," it also compels individuals seeking such relief to comply with the Act's no-fault compensation program. *See Lowry*, 189 F.3d at 1381 (citation omitted). One of the procedural components requires a claimant to first seek redress in the specialized United States Court of Federal Claims (the "Vaccine Court") before attempting to obtain relief in a court of general jurisdiction. *Moss*, 381 F.3d at 503. Congress established that "[t]he United States Court of Federal Claims and the United States Court of Federal

Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine" if a claimant is entitled to compensation under the Vaccine Act. 42 U.S.C. § 300aa-12(a). The decisions of the special masters are subject to review by the Court of Federal Claims. *Id.* § 300aa-12(e)(1). The decisions of the Court of Federal Claims are, in turn, subject to review by the United States Court of Appeals for the Federal Circuit. *Id.* § 300aa-12(f). Upon the issuance of a judgment, either by the Court of Federal Claims or by the Court of Appeals for the Federal Circuit on appeal, a claimant may elect to decline any award granted and pursue relief under traditional tort principles in state or federal court. IFN31 *Id.* § 300aa-21(a); *see Terran ex rel.. Terran v. Sec'v of Health & Human Servs.*, 195 F.3d 1302, 1307 (Fed.Cir.1999) ("[T]he Vaccine Act does not preclude traditional tort remedies. A person claiming injury due to a vaccine is required to seek redress first through the Vaccine Act, but if she is not satisfied with the result, she may reject the judgment and litigate her claim in federal or state courts, subject to certain limitations imposed by the Vaccine Act."); *see also Moss*, 381 F.3d at 503.

In its order, the district court determined that it lacked subject matter jurisdiction over Appellants' suit because Appellants failed to file a petition in the Vaccine Court before filing their civil suit in district court. Having carefully reviewed the entire record of this case, and having fully considered the parties' respective briefing and arguments, we find no reversible error in the district court's order. We therefore AFFIRM the final judgment of the district court dismissing Appellants' case for the reasons stated in its order. **AFFIRMED.**

FN* Pursuant to 5TH CIR. R. 47.5, the Court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CR. R. 47.5.4.

FN2. At the time of the alleged incident, Wyeth was known as Lederle Laboratories. For purposes of consistency and clarity, we refer to Appellee as Wyeth.

FN3. Pursuing further recourse in a court of general jurisdiction is also available in the event the claimant does not prevail in either the Court of Federal Claims or the Court of Appeals for the Federal Circuit.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

5:02-CV-265-DF

FIDEL ROMERO, Next Friend of Susana Romero, a minor; ANDREA ROMERO, Next Friend of Susana Romero, a minor
Plaintiffs - Appellants

v.

WYETH, previously known as Lederle Laboratories, et al.
Defendant - Appellee

Filed Sept. 10, 2004

ORDER

Before the Court is Defendant Wyeth's Motion to Dismiss for Failure to State a Claim Due to Lack of Compliance with the National Childhood Vaccine Injury Act, filed January 15, 2004 (Dkt. No. 30). Wyeth moves the Court to dismiss Plaintiffs' claims under FED. R. Civ.

P. 12(b)(6) because Plaintiffs allegedly failed to comply with the mandatory requirements of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 et seq. ("Vaccine Act").

STATEMENT OF ISSUES

The issue before the Court is whether this Court has jurisdiction to adjudicate Plaintiffs' vaccine-related claims when the claims were not first brought before the Court of Federal Claims.

FACTUAL BACKGROUND

Susana Romero was born on October 5, 1990. On December 12, 1990, Susana Romero received a DPT (diphtherialpertussis/tetanus) vaccine manufactured by Defendant Lederle Laboratories, now known as Wyeth. Susana suffered an immediate brain injury and began to seize thirty minutes after she was injected with Lederle's DPT. Her seizures have never been controlled.She is severely mentally retarded, unable to walk, and must be pushed in a wheel chair. In addition, Susana is unable to eat and must be fed through a gastric tube.

Plaintiffs Fidel and Andrea Romero file this action on behalf of their daughter. Alleging theories of negligence, strict liability, and gross negligence, Plaintiffs seek damages for Susana, including: (1) past and future medical expenses; (2) past and future pain, suffering, and mental anguish; (3) past and future loss of enjoyment of life; (4) past and future impairment; (5) past and future

disfigurement; (6) loss of earning capacity; and (7) punitive damages.

PROCEDURAL HISTORY

Plaintiffs filed their original complaint on December 3, 2002 (Dkt. No. 1). Defendants filed a previous motion to dismiss on December 20, 2002. In an Order dated September 17, 2003 (Dkt. No. 25), the Court denied without prejudice Defendants' motion to dismiss and allowed Defendants to conduct discovery for ninety (90) days to determine whether the plaintiffs expended and/or incurred greater than $1,000 of unreimbursable expenses during the relevant three-year statute of limitations period from December 12, 1990, to December 12, 1993. Defendants' current motion is, in part, the result of that discovery.

RULE 12(b)(6) STANDARD

As stated, Wyeth moves the Court to dismiss plaintiffs' claims under Rule 12(b)(6) because Plaintiffs allegedly failed to comply with the mandatory requirements of the Vaccine Act. In considering a motion to dismiss a complaint for failure to state a claim under Rule 12(b)(6), the Court must accept as true the non-movant's well-plead factual allegations and any reasonable inferences to be drawn from them. Tuchman v. DSC Communications Corp., 14 F.3d 1061, 1067 (5th Cir. 1994). A plaintiffs "complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355

U.S. 41, 45-46 (1957); see Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ("The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims."); Heimann v. Nat'l Elevator Industry Pension Fund, 187 F.3d 493, 502 (5th Cir.1999) (court may dismiss a claim under I2(b)(6) only if "it appears that no relief could be granted under any set of facts that could be proved consistent with the allegations.") (quoting Barrientos v. Reliance Standard Life Ins. Co., 911 F.2d 1115 (5th Cir. 1990).

DISCUSSION

Accepting as true the Plaintiffs' well-plead factual allegations and any reasonable inferences therefrom, Plaintiffs allege a valid cause of action against Defendants because their complaint claims the parties are diverse and an amount in controversy in excess of $75,000 as required by 28 U.S.C. § 1332 (1996). P. Orig. Pet. at ¶¶ 1-4. Based on Susana's injuries, Plaintiffs claim negligence, strict tort liability, and gross negligence causes of action, as well as damages, against Defendants. Id. at ¶¶ 11-24. Accordingly, based on the plain language of Plaintiffs complaint, the complaint should not be dismissed for failure to state a claim because it appears the Plaintiffs can prove a set of facts in support of their claim that would entitle them to relief.

Although a Rule 12(b)(6) motion to dismiss, Wyeth's motion raises the issue of subject matter jurisdiction because an alleged failure to comply with the Vaccine Act denies this court of jurisdiction over Plaintiffs' claims. Therefore, Wyeth' s motion would have been more

appropriately brought under Rule 12(b)(1). However, the Court, sua sponte, i.e., by its own motion, may raise and specifically address subject matter jurisdiction issues any time during the course of a case. See Zahn v. Intl Paper Co., 414 U.S. 297, 295-96 (1973) (discussing with approval Clark v. Paul Gray, Inc., 306 U.S. 583, 589 (1939)); Westland Oil Dev. Corp. v. Summit Transp. Co., 481 F. Supp. 15, 19 (S.D. Tex. 1979) (citing Burgess v. Charlottesville Say. & Loan Ass'n, 477 F.2d 40, 42 (4th Cir.1973)); WRIGHT AND MILLER, FEDERAL PRACTICE AND PROCEDURE, § 1350, at 545 (1969)); see also 5A WRIGHT AND MILLER, FEDERAL PRACTICE AND PROCEDURE, § 1350, at 202 (1990) ("[L]ack of subject matter jurisdiction may be asserted at any time by the court, sua sponte, either at the trial or appellate level.").

I.The Vaccine Act

Congress passed the Vaccine Act in 1986, recognizing that "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken."[1] "Vaccinations have "prevented thousands of children's deaths each year and have substantially reduced the effects resulting from disease." [2]

The Vaccine Act created a no-fault compensation system for injuries allegedly associated with childhood

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[1] H.R. Rep. No. 99-908, at 4 (1986), 1986 U.S.C.C.A.N. 6345.

[2] Id.

vaccines.[3] Its purpose is to provide claimants a just and efficient remedy, while also protecting vaccine manufacturers from excessive litigation costs. The Act establishes a mandatory procedure for the adjudication of claims in a forum (the "Vaccine Court") before special masters appointed by the United States Court of Federal Claims.

II. Subject Matter Jurisdiction

Until 1998, the Vaccine Act required petitioners seeking compensation through the Vaccine Compensation Program to demonstrate they had "incurred" greater than $1,000 in unreimbursable expenses. 42 U.S.C. § 300aa-11(c)(1)(D)(I) (1993). In 1998, that requirement was eliminated, which allowed victims of vaccine-related injuries to file claims in the Vaccine Court without regard to the amount of unreimbursable expenses they incurred. Pub. L. No. 105-277, § 1502, 112 Stat. 2681-741 (1998). The amendment applied to cases pending at, and filed after, the time of its enactment. See Lowry v. Sec. of HHS, 189 F.3d 1378, 1381 (Fed. Cir. 1999) (explaining same and stating the 1998 version "furthers Congress' purpose of providing an economic alternative to traditional tort suits by encouraging participation in the program and keeping potential plaintiffs in the system.").

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[3] 42 U.S.C. §§ 300aa-11 to 300aa-34 (2000). The compensation program is known formally as the National Vaccine Injury Compensation Program ("Vaccine Compensation Program"). 42 U.S.C. § 300aa-10(a) (1994).

Under both the current and pre-1998 ("superceded") versions of the Vaccine Act, section 300aa-11(a)(2)(A) erects a bar to bringing a civil action, unless a claimant first files a claim in the Vaccine Court and exhausts the remedies of the Court. The section sets out the "General Rule" for filing petitions as follows:

> No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and--(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and (II) such person elects under section 300aa-21(a) of this title to file such an action . . . .

42.U.S.C. § 300aa-11(a)(2)(A) (2000). This Court is of the opinion that Congress intended for all persons "who [have] sustained a vaccine-related injury or death and who [are] qualified to file a petition for compensation under the [Vaccine Compensation] Program" to first file a petition in the

Court of Federal Claims to seek recovery of amounts greater than $1,000. 42 U.S.C. § 300aa-11(a)(9) (2000).

Even though the issue before the Supreme Court in International Longshoremen's Association, AFL-CIO v. Davis, 476 U.S. 378 (1986), is whether federal labor laws preempt state law, an analogy may be drawn between the present case and Davis. The Supreme Court in Davis states: "It is clearly within Congress' powers to establish an exclusive federal forum to adjudicate issues of federal law in a particular area that Congress has the authority to regulate under the Constitution." Id. at 388. The Court, citing Garner v. Teamsters, 346 U.S. 485 (1953), further articulates what has come to be the accepted basis for the broadly preemptive scope of the National Labor Relations Act:

> Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. It went on to confide primary interpretation and application of its rules to a specific and specially constituted tribunal and prescribed a particular procedure for investigation, complaint and notice, and hearing and decision, including judicial relief pending a fmal administrative order. Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety oflocal procedures and attitudes toward labor controversies . . . A multiplicity of tribunals and a diversity of procedures are quite

> as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.

Id. at 490-491.

The Davis Court therefore concluded, based on Congress's requirements, that "courts are not primary tribunals to adjudicate such issues. It is essential to the administration of the Act that these determinations be left in the first instance to the National Labor Relations Board ["NLRB"]." Davis, 476 U.S. at 390 (citing San Diem Bldg. Trades Council v. Garmon, 359 U.S. 236, 244-45 (1959)). The Court further held that Congress intended that when issues are raised that should properly be presented to the NLRB, "the States as well as the federal courts must defer to the exclusive competence of the [NLRB] if the danger of state interference with national policy is to be averted." Id. (citing Garmon, 359 U.S. at 245). See also Davis, 476 U.S. at 391 ("[I]n enacting the NLRA Congress intended for the Board generally to exercise exclusive jurisdiction in [its] area."); id. at 392 ("[W]hen a particular issue has been placed by Congress within the primary and exclusive jurisdiction of the NLRB, a state court will have no subject matter jurisdiction to adjudicate the issue."). Thus, the Supreme Court held, based on the requirements established by Congress, that the NLRA divested the courts of jurisdiction.

Congress similarly established the Vaccine Court as an exclusive federal forum to first adjudicate vaccine-related injuries before a party files a civil action in another state or federal district court. In establishing the Vaccine Court,

Congress intended to provide a central forum with developed expertise and familiarity with the Vaccine Act to uniformly interpret and apply the Act to claims brought before the Court.

Accordingly, if subsection 11(a)(2)(A) applies to Plaintiffs' claim, under subsection 11(a)(2)(B), Congress mandates this Court dismiss Plaintiffs' suit. See 42 U.S.C. § 300aa-11(a)(2)(B) ("If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action."). As stated by the Federal Circuit in Black v. Secretary of Health and Human Services, 93 F.3d 781(Fed. Cir. 1996),

> [even though] the fundamental purpose of the Vaccine Act is to provide generous financial compensation for victims of severe vaccine-related injuries, ... it is not a court's function to disregard a statutory provision . . . whenever the provision produces a result in a particular case that is contrary to what the court discerns as the general purpose underlying the statute. See Weinberger v. Salfi, 422 U.S. at 777, 95 S. Ct. at 2472 (the constitutional question "is not whether a statutory provision precisely filters out those, and only those, who are in the factual position which generated the congressional concern reflected in the statute"). Absent outright irrationality, the task of refining a statutory scheme such as the Vaccine Act so that it more precisely accords with the purposes for which the Act was

> designed is the responsibility of Congress, not the courts.

Id. at 789.

Plaintiffs argue their claims do not fall within the jurisdiction of the Vaccine Act because they did not incur $1,000 in unreimbursable vaccine-related expenses. Thus, they are not required to file a petition in the Vaccine Court and may file a civil action in this Court, seeking damages for Susana's injuries. The following cases illustrate that Congress requires that persons who allege vaccine-related injuries are to first file a petition in the Vaccine Court for a determination of whether the Act applies to them before they file a civil action in state or federal court.

Although the question in Shalala v. Whitecotton, 514 U.S. 268 (1995), was one of causation, ie whether a claimant made a prima facie case for compensation under the Vaccine Act, the Supreme Court explained that:

> A claimant alleging that more than $1,000 in damages resulted from a vaccination after the Act's effective date in 1988 must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any de novo civil action in state or federal court. 42 U.S.C. § 300aa-11(a) (1988 ed. & Supp. V).

Id. at 270.

Following Congress's requirements in Haggerty v. Wyeth Averst Pharmaceuticals, 79 F. Supp. 2d 182

(E.D.N.Y. 2000), the court remanded a case originally brought by plaintiffs in state court, asserting claims under the Vaccine Act. In its Order granting remand, the court explained:

> The Act establishes a scheme of recovery for injuries and deaths traceable to vaccinations, which is designed to work faster and with greater ease than the civil tort system. Shalala v. Whitecotton, 514 U.S. 268, 269, 115 S. Ct. 1477, 131 L. Ed. 2d 374 (1995). As described by the Court in Whitecotton, the scheme provides that claims are heard in the first instance by special masters, adjudicated informally, and then accorded expeditious review. Id. at 270, 115 S. Ct. 1477. The Act achieves its objective of streamlining the claims process in large part by the establishment of standards of proof, under which patients who are administered a vaccine, and who suffer injuries within specified intervals after, have the benefit of a presumption that their symptoms were caused by the vaccine. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i); 300aa-13(a)(1); 300aa-14.

Id. at 184.

Supporting Congress's scheme that claims are heard in the first instance by special masters, one of the Vaccine Court's special masters held in Jessen v. Sec. of HHS, No. 94-1029V, 1997 WL 48940 (Ct. Cl. Jan. 17, 1997) that:

> [P]ersons who ... believe they have been harmed by a vaccination administered after October 1, 1988 are required to file a Program claim, before filing a tort suit against either the vaccine administrator or manufacturer. See § 300aa-11(a)(2). It seems to me that, faced with that requirement, a person in petitioner's situation, with an apparently meritorious claim of a vaccine-related injury, has no choice but to file a Program claim and advance the best argument that she can concerning the $1000 requirement, even if her argument on that $1000 issue is of questionable merit. Only when her argument concerning the $1000 has been advanced and rejected in the Program proceeding is she legally free to pursue a tort claim.

Jessen, 1997 WL 48940, at *3. Further supporting Congress's scheme, the court in May v. Secretary of Health and Human Services, No. 91-1057V, 1995 WL 298554 (Ct. Cl. May 2, 1995), decided whether to award damages in an action brought under the Vaccine Compensation Program. Doing so, the court explained:

> Under the federal statute establishing the Program, a petitioner injured by a vaccination administered after October 1, 1988, must first file a Program petition, and obtain a decision on that petition, prior to filing any tort suit against the vaccine manufacturer or administrator. (If a Program award is obtained and accepted by

> the petitioner, then no tort suit may be filed. If no award is obtained or the petitioner obtains an award but elects to reject it, a tort suit may then be filed.) See §§ 300aa-11(a), 300aa-21. Accordingly, when a person files a Program petition, any state law limitations period for filing a tort suit related to the same vaccination is tolled from the date that the petition is filed until the conclusion of the Program proceeding. § 300aa-16(c).

Id. at * 8 n.3.

Plaintiffs argue the Fifth Circuit's recent ruling in Moss v. Merck & Co., No. 03-30958, 2004 WL 1814082 (5th Cir. Aug. 16, 2004), is favorable to their position. The district court in Moss dismissed plaintiff's case under Rule 12(b)(1) on the ground the Vaccine Act precluded the plaintiffs' pursuit of a tort remedy for a vaccine-related injury. Id. at *1. The Fifth Circuit reversed because Defendant Eli Lily, the manufacturer of Thimerosal, was not found to be a vaccine manufacturer as defined at 42 U.S.C. § 300aa-33(3) because Thimerosal is not a vaccine. Id. at *2.

The Vaccine Act applies to claims for "injuries, disabilities, illnesses, [and] conditions" associated with one or more of the vaccines set forth in the Vaccine Injury Table. 42 U.S.C. § 300aa-14 (1993). Wyeth's DTP vaccine is now, and was at the time of Susana's vaccination, listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-14 (1986) (original table); 42

C.F.R. § 100.3 (2002) (current table). The Fifth Circuit's findings in Moss, therefore, are inapplicable to the present dispute.

Plaintiffs are suing for "vaccine-related injuries" as defined by the Vaccine Act in that Plaintiffs claim Susana experienced an acute and severe reaction to the DTP vaccine. They are suing for an amount greater than $1,000. Complaint at ¶ 3. Subsection 11(a)(2)(A) therefore applies to Plaintiffs' claims.

Plaintiffs readily admit they did not file a petition in the Vaccine Court. As mandated by Congress and the Vaccine Act, this Court must dismiss Plaintiffs' claims under subsection 11(a)(2)(B). With the dismissal of Plaintiffs' claims, the Court is without subj ect matter jurisdiction to reach the issue of whether Plaintiffs incurred $1,000 in vaccine-related expenses under the current or superceded versions of the Act.

CONCLUSION

There exists no doubt Susana Romero suffers from a severely debilitating condition, probably the result of the DPT vaccine she received. The Court is highly sympathetic to Susana's condition that she has suffered with for most of her life. The Court, however, is in the difficult position of having to weigh the needs of the Plaintiffs against the requirements of Congress and established precedent. Although not a usual practice of this Court, given the difficult facts of this case and the

grave injuries suffered by Susana Romero, the Court welcomes an appeal from this decision to determine whether the Court has correctly interpreted the provisions of the Vaccine Act.

The Court finds it does not have subject matter jurisdiction over Plaintiffs' claims because Plaintiffs failed to comply with the requirements of the Vaccine Act before filing a civil action in this Court. Wyeth files their motion to dismiss under Rule 12(b)(6) for Plaintiffs' failure to state a claim upon which relief may be granted. Subsection 11(a)(2)(B) of the Act requires the dismissal of this action. For this reason, the Court lacks jurisdiction over the claims presented by Plaintiffs. The Court therefore ORDERS this case be DISMISSED WITH PREJUDICE due to its lack of subject matter jurisdiction over Plaintiffs' claims.

SIGNED this 10th day of September 2004.

DAVID FOLSOM
UNITED STATES DISTRICT JUDGE

APPENDIX D

42 U.S.C.A. § 300aa-11. Petitions for compensation

(a) General rule.

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and--

(i) (I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart.

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this subpart damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on the effective date of this subpart has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this subpart or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(8) If on the effective date of this subpart there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners.

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this subpart if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content. A petition for compensation under the Program for a vaccine-related injury or death shall contain--

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died--

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine,

contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table-
(I) received the vaccine in the United States or in its trust territories,
(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or
(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of

the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000, or (ii) died from the administration of the vaccine, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results,
and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information. A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule. The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(2)

Supreme Court, U.S.
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No. 05-1298

IN THE

Supreme Court of the United States

FIDEL ROMERO, *et ux.*, next friends of SUSANA ROMERO, a minor,

Petitioners,

v.

WYETH, fka LEDERLE LABORATORIES,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. The Vaccine Act requires a claim for vaccine-related injury to be filed initially in Vaccine Court and to be exhausted there before any civil action arising from that vaccine-related injury may be filed in any court. May a claimant avoid Vaccine Court, and the exhaustion requirement, by filing a civil action in federal district court and litigating there his qualification to file in Vaccine Court?

2. Should this Court consider a constitutional argument that was waived in the Court below and that could have been raised in Vaccine Court and heard in the United States Court of Appeals for the Federal Circuit on appeal from Vaccine Court?

3. Does the Vaccine Act provide claimants an opportunity to have adjudicated in an Article III court issues arising under the Vaccine Act, including their qualification to file in Vaccine Court?

STATEMENT PURSUANT TO RULE 29.6

Respondent, Wyeth, fka Lederle Laboratories, has no parent corporation and no publicly held company owns 10% or more of its stock.

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1. The Vaccine Act expressly confers on the Vaccine Court the authority to resolve qualification issues. 8

2. Claimants must present issues regarding an administrative agency's jurisdiction to the agency in the first instance. 10

3. This case is not about implied preemption. 13

B. The Court should not consider plaintiffs' Article III argument because it was not raised below, and because it lacks merit. 14

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ABBREVIATIONS AND CITATIONS TO THE RECORD

Petitioners are referred to as "plaintiffs."

Respondent is referred to as "Wyeth."

Citations to plaintiffs' Appendix to their Petition for Writ of Certiorari are denoted "Pl. App." followed by the tab and page number.

Citations to the record on appeal are denoted "R." followed by the USCA5 page number.

"Vaccine Act" refers to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 *et seq.*

"Vaccine Court" refers to the administrative tribunal consisting of the United States Court of Federal Claims and its special masters, which together have jurisdiction over proceedings to determine if a petitioner is entitled to compensation under the Vaccine Act.

STATEMENT OF THE CASE

Plaintiffs filed suit in federal district court on December 3, 2002 claiming their daughter's seizure disorder was caused by a DPT vaccine administered twelve years previously. Plaintiffs did not mention the Vaccine Act, which requires all claims for vaccine-related injury to be presented (and exhausted) in a specialized Vaccine Court before a civil action may be commenced on any claim arising from the alleged injury. Plaintiffs here had not petitioned in Vaccine Court. Because plaintiffs' claim was for a "vaccine-related injury" and had not been exhausted, Wyeth moved under FED. R. CIV. P. 12(b)(6) to dismiss in accordance with § 300aa-11(a)(2)(A) of the Vaccine Act. As relevant here, that section of the Act bars any court from entertaining any civil action against a vaccine manufacturer, that arises from a vaccine-related injury, unless the Vaccine Act remedy has first been exhausted. In response to Wyeth's motion, plaintiffs argued that they were not qualified to file in Vaccine Court during the applicable limitations period (December 1990 to December 1993).

Plaintiffs relied on a provision of the Vaccine Act that was repealed four years before they filed suit. The repealed provision required claimants to have "incurred" over $1,000 in unreimbursable expenses due to the alleged vaccine-related injury within the Vaccine Act's three-year limitations period to be eligible for relief in Vaccine Court. 42 U.S.C. § 300aa-11(c)(1)(D)(i) (repealed 1998). Citing a terse, four-paragraph affidavit from parent plaintiff Fidel Romero, plaintiffs claimed that they had not "expended" $1,000 for their daughter's care during the relevant time and thus had not been "qualified" to file suit in Vaccine Court.

After a hearing, the district court denied Wyeth's motion to dismiss without prejudice and allowed the parties to conduct discovery on the $1,000 issue. Because the relevant medical care had been provided nine or more years earlier, the medical records were spotty at best. Wyeth nevertheless uncovered evidence that the plaintiffs actually had incurred well over $1,000 in unreimbursable medical charges from a single clinic and submitted that evidence in further support of the motion to dismiss. R. at 255-60. (The plaintiffs themselves admitted that they had paid out of pocket over $500. R. at 421, 424.)

In an Order signed September 10, 2004, the court dismissed plaintiffs' claims on the ground that their failure to exhaust administrative remedies deprived the court of jurisdiction to hear the qualification issue: "Congress requires that persons who allege vaccine-related injuries are to first file a petition in the Vaccine Court for a determination of whether the Act applies to them before they file a civil action in state or federal court." Pl. App. C, 17a. The Court held that it was "without subject matter jurisdiction to reach the issue of whether Plaintiffs incurred $1,000 in vaccine-related expenses under the current or superceded versions of the Act." *Id.* at 21a. These holdings directly contradict plaintiffs' representation that "the district court accepted as true the Romero's factual contention that Susana had not satisfied the '$1,000' requirement." Petition at 3.[1]

1. The district court did "[a]ccept[] as true the Plaintiffs' well-plead[ed] factual allegations," but only for purposes of determining that their complaint was not subject to dismissal under Rule 12(b)(6) for failure to state a claim. Pl. App. C, 10a. The portion of the district court's opinion devoted to the 12(b)(6) standard merely references the plaintiffs' original complaint, which, in turn, does not mention

(Cont'd)

In a per curiam opinion, the United States Court of Appeals for the Fifth Circuit affirmed the district court's decision, finding no reversible error. Pl. App. B, 3a-6a. It denied Plaintiffs' Petitions for Rehearing and Rehearing *En Banc* without opinion. Pl. App. A, 1a-2a.

SUMMARY OF REASONS TO DENY THE PETITION

This case is not about implied preemption, sovereign immunity, or "the role of the independent judiciary within the constitutional scheme of tripartite government." Petition at 17-18. This case is about plaintiffs who failed to meet the statutory deadline for filing a vaccine-related injury petition in Vaccine Court, and their attempt to dodge that mistake nine years later by going directly to federal district court without having exhausted the Vaccine Court remedy. The Fifth Circuit relied on the provisions of the Vaccine Act itself and on settled principles of administrative law to reject the plaintiffs' attempted circumvention of the Vaccine Act's exhaustion of remedies requirement.

Even if the lower court were wrong, however, plaintiffs' twelve-year-old claim involves a provision of the Vaccine Act that was repealed eight years ago and unique circumstances not addressed by any court before or since its dismissal in 2004. It is highly unlikely that the lower court's decision will affect any plaintiffs other than the Romeros, and the decision does not merit review by this Court. While

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the Vaccine Act or its requirements. *See id.* The district court then proceeded to address Wyeth's jurisdictional arguments. *See id.* at 10a-11a. It ultimately determined that it could not reach the $1,000 issue for want of jurisdiction. *Id.* at 21a.